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510(k) SUMMARY

Water*Check*™ CP
Reagent Strip for Chlorine and Peroxide

SUMITTER:

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DEVICE NAME:

Trade Name: **Water*Check*™ CP**
Common Name: Reagent Strip for Chlorine and Peroxide
Classification Name:

COMPARATIVE PRODUCTS:

Serim Residual Chlorine Strip - Manufactured and marketed by Serim Research Corporation, Elkhart, IN 46514
Renalin Residual Test Strips- Marketed by Renal Systems, Minneapolis, MN 55447

DESCRIPTION OF THE NEW DEVICE:

Water*Check*™ CP Reagent Strip is a paper based dry chemistry reagent strip. It consists of a single reagent pad, 0.2x0.2 inch square, adhered to one end of a 0.2x2.5 inch plastic handle with a double sided adhesive. The chemistry of the regent strip allows the same single reagent pad to react with either chlorine or peroxide. It is self-contained and is ready to use as a dip-and-read reagent strip without other additional reagent.

INTEDED USE:

Water*Check*™ CP Reagent Strip is intended to be used in detecting residual chlorine or peroxide in dialysis water. It also is used for detection of effective high level of chlorine in the disinfecting solution.

TECHNOLOGICAL COMPARISON:

For reaction with chlorine, both Water*Check*™ CP and Serim Residual Chlorine Strips are based on oxidation of a chromogenic indicator by chlorine. In Serim Strip, redox indicator, syringaldazine, is used in the strip formulation and it will turn purplish red when dip in chlorine solution. In Water*Check*™ CP strip, the redox indicator used is 3,3'5.5'-tetramethylbenzidine (TMB). The strip will turn blue in the presence of low level of chlorine. Both strips can detect chlorine level at 0.5 ppm or less. Since TMB will turn brown at a higher oxidation state, Water*Check*™ CP has also utilized this color shift to extended its detection range to high level of chlorine, 1000 ppm or more, where effective chlorine level is used for disinfection.

For reaction with peroxide, both Water*Check*™ CP and Renalin Test Strips are based on catalytic oxidation of 3,3'5,5'-tetramethylbenzidine (TMB) by hydrogen peroxide and acetyl peroxide. Both strips will detect as low as 1 ppm of hydrogen peroxide. Water*Check*™ CP, however, is stable at room temperature and is sensitive to 0.5 ppm or less of hydrogen peroxide. On the other hand, Renalin Test Strip requires refrigeration and is practically insensitive to 0.5 ppm of hydrogen peroxide.

SUBSTANTIAL EQUIVALENCE STATEMENT:

Both Water*Check*™ CP and Serim Residual Chlorine Strips are equally effective in detecting 0.5 ppm or less of residual chlorine. Water*Check*™ CP can further detect high level, 1000 ppm or more, of chlorine in disinfecting solution.

Both Water*Check*™ CP and Renalin Test Strip are equally effective in detecting 1.0 ppm of hydrogen peroxide. Water*Check*™ CP, however, is more effective over Renalin Strip in that Water*Check*™ CP is stable at room temperature and is sensitive to 0.5 ppm or less of hydrogen peroxide.

Submitter: Wen H. Wu Date: Aug 23 95
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